

K133329

NOV 27 2013

510(k) Premarket Notification

UGEO WS80A Diagnostic Ultrasound System

### 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

#### 1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMUNGMEDISON CO., LTD.  
42, Teheran-ro 108-gil, Gangnam-gu,  
Seoul, Korea

**Contact Person:**  
Kyeong-Mi, Park  
Regulatory Affairs Manager

Telephone: 82.2.2194.1373  
Facsimile: 82.2.556.3974

**Data Prepared:** September 2, 2013

#### 2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

UGEO WS80A Diagnostic Ultrasound System

<u>Classification Names:</u>	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

#### 3. Identification of the predicate or legally marketed device:

- ACCUVIX A30 Diagnostic Ultrasound System(K112339)
- UGEO HM70A Diagnostic Ultrasound System(K130803)
- ACCUVIX XG Diagnostic Ultrasound System (K103397)
- ACUSON S2000 Diagnostic Ultrasound System (K130739)
- iU22 Diagnostic Ultrasound System (K093563)

※ The proprietary name of predicate device (K130803) was changed to UGEO HM70A Diagnostic Ultrasound System from UGEO H70c Diagnostic Ultrasound System on FDA Databases

#### 4. Device Description:

The UGEO WS80A is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode: S-Flow), PW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real time 4D imaging mode) or as a combination of these modes. The UGEO WS80A also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The UGEO WS80A has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

#### 5. Intended Uses:

The UGEO WS80A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Small Organs, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial) and Peripheral vessel.

#### 6. Technological Characteristics:

The UGEO WS80A is substantially equivalent with respect to safety, effectiveness, and functionality to the ACCUVIX A30 Diagnostic Ultrasound System (K112339) and UGEO HM70A Diagnostic Ultrasound System (K130803).

It is substantially equivalent with respect to safety, effectiveness, and functionality to the [3D Cine, HDVI and Volume NT] of SAMSUNG MEDISON's UGEO HM70A (K130803) in regards to the device with [5D Cine<sup>1)</sup>, FRV<sup>2)</sup>, 5D NT<sup>3)</sup> and 2D NT<sup>4)</sup>].

It is substantially equivalent with respect to safety, effectiveness, and functionality to the [Syngo Auto OB Measurements] of Siemens's ACUSON S2000 (K130739) in regards to the device with [5D LB (Long Bone)<sup>5)</sup>].

It is substantially equivalent with respect to safety, effectiveness, and functionality to the [High Q Automatic Doppler Analysis] of Philips's iU22 (K093563) in regards to the device with [MPI<sup>6)</sup>].

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

These are described in detail in the technological characteristics comparison table as below.

&lt;Technological Characteristics Comparison Table&gt;

Feature / Characteristics	The subject device	The predicate devices				
	UGEO WS80A	ACCUVIX A30 (K112339)	UGEO HM70A (K130803)	ACCUVIX XG (K103397)	ACUSON S2000 (K130739)	iU22 (K093563)
Indication for Use						
- Fetal	√	√	√	√	√	√
- Abdominal	√	√	√	√	√	√
- Pediatric		√	√	√	√	√
- Small Organ	√	√	√	√	√	√
- Neonatal Cephalic		√	√	√	√	√
- Adult Cephalic		√	√	√	√	√
- Trans-rectal	√	√	√	√	√	√
- Trans-vaginal	√	√	√	√	√	√
- Musculo-skeletal (Conventional)	√	√	√	√	√	√
- Musculo-skeletal (Superficial)	√	√	√	√	√	√
- Cardiac Adult		√	√	√	√	√
- Cardiac Pediatric		√	√	√	√	√
- Peripheral vessel	√	√	√	√	√	√
Scanhead Types						
- Linear Array	√	√	√	√	√	√
- Curved Linear Array	√	√	√	√	√	√
- Endocavity	√	√	√	√	√	√
- Phased Array		√	√	√	√	√
- Static Probes		√	√	√	√	√
Scanhead Frequency						
1.0 ~ 20.0 MHz	√	√	√	√	√	√
Modes of Operation						
- B-mode	√	√	√	√	√	√
- M-mode	√	√	√	√	√	√
- Pulsed wave (PW) Doppler	√	√	√	√	√	√
- Continuous wave (CW) Doppler		√	√	√	√	√
- Color Doppler	√	√	√	√	√	√
- Power Amplitude Doppler	√	√	√	√	√	√
- Tissue Harmonic Imaging	√	√	√	√	√	√
- 3D/4D imaging mode	√	√	√	√	√	√
- Combined modes	√	√	√	√	√	√
Safety & EMC Compliance						
- IEC 60601-1	√	√	√	√	√	√
- UL 60601-1						
- CSA C22.2 No.601.1						
- IEC 60601-2-37	√	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√	√
Acoustic Output Display Standard						

Feature / Characteristics	The subject device	The predicate devices				
	UGEO WS80A	ACCUVIX A30 (K112339)	UGEO HM70A (K130803)	ACCUVIX XG (K103397)	ACUSON S2000 (K130739)	iU22 (K093563)
Track 3	√	√	√	√	√	√
Patient Contact Materials						
Tested to ISO 10993-1	√	√	√	√	√	√
Functionality						
- Quick Scan (Q Scan)	√	√	√	√		
- Spatial Compound Imaging	√	√	√	√		
- SMDR (SMDR evo)	√	√	√	√		
- Auto IMT+ (Auto IMT)	√	√	√	√		
- Elastoscanner	√	√	√	√		
- Panoramic	√	√	√	√		
- 3D Imaging (Volume Data Acquisition)	√	√	√	√		
- 3D Imaging presentation 3D Cine/4D Cine 5D Cine	√ √ <sup>(1)</sup>	√	√	√		
- 3D Rendering MPR(Multi Planer Render)	√	√	√	√		
- 3D XI MSV(Multi Slice View) Oblique View	√	√		√		
- 3D MXI Volume Slice, Mirror View	√	√	√	√		
- 3D MagiCut	√	√	√	√		
- Volume Calculation (VOCAL, XI VOCAL)	√	√	√	√		
- XI STIC	√	√	√	√		
- HDVI	√	√	√	√		
- FRV	√ <sup>(2)</sup>					
- Volume NT/IT	√	√	√	√		
- 5D NT	√ <sup>(3)</sup>					
- 2D NT	√ <sup>(4)</sup>					
- ADVR	√	√	√			
- 5D LB	√ <sup>(5)</sup>				√ <sup>(5)</sup>	
- MPI	√ <sup>(6)</sup>					√ <sup>(6)</sup>

**7. A brief discussion of the bench and non-clinical tests conducted on the subject device**

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The UGEO WS80A and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

Summary of Clinical Tests:

Not applicable. The subject of this submission, UGEO WS80A, did not require clinical studies to support substantial equivalence.

**8. Conclusion**

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the UGEO WS80A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

**END of 510(K) Summary**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

November 27, 2013

Samsung Medison Co., Ltd.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K133329  
Trade/Device Name: UGEO WS80A Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: October 28, 2013  
Received: October 29, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the UGEO WS80A Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

SC1-6	C2-6	E3-12A
VR5-9	L3-12A	L5-13
V4-8	V5-9	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

**SECTION 1.3  
INDICATIONS FOR USE**

510(k) Number (if known): K133329

Device Name: UGEO WS80A Diagnostic Ultrasound System

**Indications for Use:**

The UGEO WS80A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Small Organ, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial) and Peripheral vessel

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

*Smh.7)*

(Division Sign Off)  
Division of Radiological Health  
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K133329

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name:UGEO WS80ADiagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	N	N	N		N	Note 1	Notes 2, 4, 7, 8, 11
	Abdominal(See Note 10)	N	N	N		N	Note 1	Notes 2, 7, 8, 9, 11, 12
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 3)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Notes 2, 7, 8, 11, 12
	Trans-vaginal	N	N	N		N	Note 1	Notes 2, 7, 8, 11, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; F= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastScan

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: SCI-6 for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & II)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 11
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C2-6 for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 11
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastScan

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: E3-12A for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	N	N	N		N	Note 1	Notes 7, 8
	Abdominal (See Note 10)	N	N	N		N	Note 1	Notes 7, 8, 12
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Notes 7, 8, 12
	Trans-vaginal	N	N	N		N	Note 1	Notes 7, 8, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoSca

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: VR5-9for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal (See Note 10)	P	P	P		P	Note 1	Note 2, 7, 8, 12
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K103397; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B•M, B•PW, B•C, B•PD, B•DPD, B•PPI, B•TD, B•C•PW, B•PD•PW, B•DPD•PW, B•PPI•PW, B•TD•PW, B•C•M, Dual/Quad/B, B•C, B•PD, B•TD, B•PPI, B•PD, B•E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:

Device Name: L3-12A for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastScan

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L5-13 for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V4-8for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal (See Note 10)	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K103397; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)

### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9for use with UGEO WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal(See Note 10)	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K103397; E= added under Appendix E

## Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad(B, B+C, B+PD, B+TD, B+PPI, B+PD), B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Prescription Use (Per 21 CFR 801.109)